

REMARKS

The Office Action mailed September 27, 2006 has been received and reviewed. This response is filed with a 3 month request for extension of time and required fee. Claims 1-6, 8-13, 15-22, 38-40 and 46 are currently under consideration. Claim 6 has been canceled and incorporated into claim 1. Claim 40 has been amended. New claim 49 is added and finds support throughout the as-filed specification including, for example, the sequence listing and including paragraphs [0004] and [0035]-[0037]. All amendments and cancellations are made without prejudice or disclaimer. No new matter is added. All pending claims stand rejected. Reconsideration is respectfully requested.

35 U.S.C. §112

A. Claims 1-6, 8-13, 15, 17-20, 22, 38-40 and 46 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse the rejection.

Specifically, it was asserted that applicants failed to sufficiently describe the genus "YscF protein." The specification defined "YscF" as "the YscF protein originating from any of The specification defined "YscF" as "the YscF protein originating from any of *Y. pestis*, *Y. pseudotuberculosis*, *Y. enterocolitica* unless otherwise specified. The YscF proteins of *Y. pestis* and *Y. enterocolitica* include substantially similar sequences as indicated in the alignment of FIG. 1. Further, since many proteins of the type III secretion complex of both *Y. pestis* and *Y. pseudotuberculosis* are substantially similar, YscF from *Y. pestis* and *Y. pseudotuberculosis* are considered to be substantially similar." (Specification, page 9, paragraph [0032]). The specification in paragraphs [0033]-[0037] further details the distinguishing attributes shared by members of the genus. FIG. 1 further provided a sequence alignment of peptide sequences of the YscF protein from various *Yersinia* bacteria. Accordingly, one of skill in the art would reasonably conclude that the disclosure provides a representative number of species to describe the genus. Reconsideration and withdrawal of the rejection is thus respectfully requested.

B. Claims 1-6, 8-13, 15-21 and 38-40 stand rejected under 35 U.S.C. §112, first paragraph, because the specification, while admittedly enabling for immunogenic compositions, allegedly failed to provide enablement for compositions capable of providing protection against a pathogen of *Yersinia* origin. Applicants respectfully traverse the rejection.

The specification includes numerous examples wherein YscF is overexpressed, purified and used as a protective antigen. (*See e.g.*, Specification, paragraph [0038]-[0056]). YscF immunization triggered an antibody response to YscF and that antibody response afforded significant protection to immunized mice following challenge with *Y. pestis*. (Specification, paragraph [0042]-[0049]). Thus, the as-filed application provides enablement for a composition capable of providing protection against a pathogen of *Yersinia* origin. Reconsideration and withdrawal of the rejection is thus requested.

C. Claim 40 stands rejected under 35 U.S.C. §112, second paragraph, as being allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants have amended claim 40 to recite “The isolated or recombinant YscF protein of claim 20, wherein the isolated or recombinant YscF protein is encoded by a nucleotide sequence having at least 80% identity to SEQ ID NO: 1.” Support for the amendment may be found throughout the as-filed specification including, for example, FIG. 1 and related text including paragraphs [0004] and [0035]-[0037]. Reconsideration and withdrawal of the rejection is thus requested.

35 U.S.C. §102(b)

A. Claims 1-3, 5-6, 8-11, 13, 15, 17-18, 20, 22, 38-40 and 46 stand rejected under 35 U.S.C. §102(b) as being allegedly anticipated by Titball et al. (U.S. Patent 5,985,285). Applicants respectfully traverse the rejection.

Titball describes subunit vaccines against the F1 capsular antigen and the V antigen (also known as LcrV) of *Y. pestis*. By contrast, each of the independent claims includes YscF protein which is not described, either expressly or inherently, by Titball. As stated herein, the specification describes “YscF” as a YscF protein originating from of *Y. pestis*, *Y. pseudotuberculosis*, *Y. enterocolitica* unless otherwise specified. The YscF proteins of *Y. pestis*

and *Y. enterocolitica* include substantially similar sequences as indicated in the alignment of FIG.

1. Further, since many proteins of the type III secretion complex of both *Y. pestis* and *Y. pseudotuberculosis* are substantially similar, YscF from *Y. pestis* and *Y. pseudotuberculosis* are considered to be substantially similar.” (Specification, paragraph [0032]). Titball lacks any disclosure of a YscF protein. Accordingly, Titball cannot anticipate the present claims. Reconsideration and withdrawal of the rejection is requested.

B. Claims 1, 8 and 22 stand rejected under 35 U.S.C. §102(b) as being allegedly anticipated by Stewart Jr. et al. (U.S. Patent 6,261,561). Applicants respectfully traverse the rejection.


Stewart Jr. describes a plasmid pHis-Inv1 encoding a His-tagged *Yersinia pseudotuberculosis*. By contrast, each of the independent claim 1 and 22 includes YscF protein which is not described, either expressly or inherently, by Stewart Jr. As stated herein, the specification describes “YscF” as a YscF protein originating from of *Y. pestis*, *Y. pseudotuberculosis*, *Y. enterocolitica* unless otherwise specified. The YscF proteins of *Y. pestis* and *Y. enterocolitica* include substantially similar sequences as indicated in the alignment of FIG.

1. Further, since many proteins of the type III secretion complex of both *Y. pestis* and *Y. pseudotuberculosis* are substantially similar, YscF from *Y. pestis* and *Y. pseudotuberculosis* are considered to be substantially similar.” (Specification, paragraph [0032]). Stewart Jr. lacks any disclosure of a YscF protein. Accordingly, Stewart Jr. cannot anticipate the present claims. Reconsideration and withdrawal of the rejection is requested.

Conclusion

In view of the foregoing amendments and remarks, applicants submit that the claims define patentable subject matter and a notice of allowance is requested. Should questions exist after consideration of the foregoing, the Office is kindly requested to contact the applicants' attorney at the address or telephone number given herein.

Respectfully submitted,



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